K060074
1 of 2

MAR 2 9 2006

1. 510(K) SUMMARY

Submitter:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

Preparer/Contact:

Nanette Hedden
Global Regulatory Affairs
1620 Waukegan Rd.
McGaw Park, IL 60085
Telephone: (847) 473-6281
Fax: (847) 784-5116

Date Summary was Prepared:

January 3, 2006

Device Name:

Trade name: Interlink T-Connector Extension Set
Common name: IV Administration Set
Classification name: Intravascular Administration Set (21 CFR 880.5440, Product Code FPA)

Predicate Device(s):

Baxter Interlink T-Connector Extension Set cleared under premarket notification K921899, cleared April 20, 1993.

Device Description:

The Interlink T-Connector Extension Set consists of an Interlink injection site integrated into a T-Housing on one end of the extension set with a female adapter connected to the other end. A slide clamp is also included on the tubing. This extension set is connected to an indwelling catheter in order to administer or withdraw fluids. The injection site is accessed by a blunt plastic cannula; this allows fluid flow while aiding in the prevention of needlestick injuries.

Statement of Intended Use:

For use in neonatal population only. To be used with an indwelling catheter for the administration or withdrawal of fluids. This device may aid in the prevention of needlestick injuries.

Summary of Technological Characteristics of New Device to Predicate Devices:

The technological characteristics of the Interlink T-Connector Extension Set do not differ significantly from the currently marketed Baxter Interlink Administration Sets. The T-Connector design allows for easy access to the catheter and easier tubing connection to the patient compared to standard extension sets. The slip connection provides an attachment method that is less likely to direct the forces of IV line attachment to the patient's sensitive catheter injection site as compared to locking collar type Luer devices. Also key to the intended population is the priming/residual volume and the flush clearance efficiency for infused drugs and for clearing blood from the device post blood sampling. Because the patient is small and commonly fluid restricted, control of the amount of fluid administered may be important. This includes medication as well as flushing or clearing the lines after medication administration.

Discussion of Nonclinical Tests:

Baxter Healthcare conducts risk analyses using procedures based on ISO 14971 (2000) "Medical Devices – Application of Risk Management to Medical Devices". The risk analysis method used to assess the impact of these modifications was Failure Modes and Effects Analysis (FMEA). Design verification tests based on the results of risk analysis and design input were performed to verify those modifications. Testing of the set and components included mechanical, biocompatibility, and microbial ingress testing. All test results met the acceptance criteria.

Conclusion:

The Interlink T-Connector Extension Set is substantially equivalent to the currently cleared Interlink T-Connector Extension Set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2006

Baxter Healthcare Corporation
C/O Ms. Nanette Hedden
Specialist
Global Regulatory Affairs
Medication Delivery
1620 Waukegan Road
McGaw Park, Illinois 60085

Re: K060074
Trade/Device Name: Interlink T-Connector Extension Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: January 9, 2006
Received: January 10, 2006

Dear Ms. Hedden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060074

1 of 1

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Interlink T-Connector Extension Set

Indications For Use: For use in neonatal population only. To be used with an indwelling catheter for the administration or withdrawal of fluids. This device may aid in the prevention of needlestick injuries.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

[illegible] General Hospital

[illegible] Devices

K060074